

KING & SPALDING

1730 PENNSYLVANIA AVENUE, N.W.
WASHINGTON, D.C. 20006-4706

TELEPHONE: 202/737-0500

FACSIMILE: 202/626-3737

9153 '02 DEC 23 P3 '49

DIRECT DIAL:

202/626-2903

EMAIL:
ebasile@kslaw.com
www.kslaw.com

December 23, 2002

VIA FACSIMILE 301-827-6870

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Request for Extension of Time regarding Docket No: 02D-0266; Draft Guidance for Industry: Preventative Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps)

Dear Sir or Madam:

We respectfully request that the comment period on the above-referenced matter be extended thirty (30) days. We are currently conducting research on available data showing the safety of imported bone and need additional time to complete this research.

Thank you for your consideration.

Sincerely,



Edward M. Basile

02D-0266

EXT 1